PATENT **BSI-210**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

82 97

Applicant:

G. Goicoechea et al.

: Art Unit:

3308

Serial No.:

08/463,987

: Examiner: M. Milano

Filed:

June 5, 1995

For:

BIFURCATED ENDOLUMINAL

PROSTHESIS

VERIFIED STATEMENT OF FACTS, BY PAUL F. PRESTIA AND ALLAN M. WHEATCRAFT, PURSUANT TO 37 C.F.R. § 1.48(a)

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

We, Paul F. Prestia and Allan M. Wheatcraft, hereby declare as follows:

- We are Attorneys in the firm of Ratner & Prestia, a 1. professional corporation. We are registered to practice before the Patent and Trademark Office, and we prepared and filed this application on June 5, 1995 and its U.S. parent applications on September 27, 1994 (U.S. Serial No. 08/312,881) and October 4, 1994 (U.S. Serial No. 08/317,763).
- 2. We prepared the parent application '763 of the present application from disclosures provided to us in August 1994. The inventorship entity supplied to us contained only the names of the three (3) co-inventors originally named in this application. Although the parent of the '763 application (Serial No. 08/312,881, of which the '763 application is a continuation-in-part) named Dr. Andrew H. Cragg as a co-inventor, our understanding at the time of filing the '763 application was that the development of the specific subject matter added by the '763 application as a CIP over its parent (the '881 application) had been developed after (and therefore without) Dr. Cragg's input. We were not consulted regarding this conclusion, nor did we perform any investigation to confirm or refute it as of the date of filing the '763 application (because there was no indication of any question regarding the inventorship at that time). Accordingly, the '763 application was filed with the original inventorship entity

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naming only the three co-inventors, and the application was assigned to the original assignee, MinTec, Inc. The present application was filed as a divisional application of the '763 application just prior to GATT-related changes.

- 3. Commencing in 1995 and culminating in the spring of 1996, MinTec, Inc. was involved in negotiating the sale of its assets to Boston Scientific Technology, Inc. During the course of these negotiations, Boston Scientific raised the question of whether the inventorship entity named in the present application was correct. On information and belief, Dr. Michael D. Dake had indicated to someone in the industry that he had contributed to the development of the invention.
- 4. In response to the question raised by Boston Scientific, we solicited proofs including documentary evidence and oral testimony from all of the named co-inventors and from Dr. Dake, as well as from Dr. Cragg, regarding the facts surrounding the development of the present invention.
- 5. To the extent we believed necessary, certain of these proofs were corroborated by statements from individuals other than the above-named co-inventors. The last of these statements was received August 8, 1996.
- 6. Based on this evidence, we concluded that Dr. Dake and Dr. Cragg were co-inventors of the present invention and were erroneously omitted from this application innocently and without deceptive intent. We then communicated this conclusion to Dr. Dake and Dr. Cragg and to all of the originally named co-inventors in the application in a letter mailed August 26, 1996, and requested any further comments or proofs regarding development of the invention by September 9, 1996.
- 7. As of September 9, 1996, we had spoken with all the originally named co-inventors and Dr. Dake and Dr. Cragg, to ensure that we had considered all of the available relevant facts.
- 8. Our conclusion was that Dr. Michael D. Dake and Dr. Andrew H. Cragg are co-inventors, with George Goicoechea, Claude Mialhe, and John Hudson, of the invention claimed in this application and that the omission of

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Dr. Dake and Dr. Cragg as named co-inventors occurred through error without any deceptive intention on anyone's part.

- 9. Accordingly, we immediately began preparing this petition for correction of inventorship, and accompanying Declarations and Verifications, to satisfy the diligence requirement of 37 C.F.R. § 1.48(a). The inventorship study also involved determination of inventorship in nine related applications directed to this technology, and the necessary documentation for changing inventorship was also prepared in six of those related applications. The situation was further complicated because the inventors are located in three different countries around the world, as well as the Bahamas, making communications difficult. Proper resolution of the inventorship issues in these cases was thus a substantial undertaking requiring much time-consuming effort and coordination.
- 10. The first set of documents requiring inventor signatures to correct the inventorship in this case was completed and shipped to the inventors on November 1, 1996. The last of these documents to be executed and returned (after oral discussions with the inventor) was received by us on December 10, 1996. Upon final review of these documents for filing with the USPTO, certain informalities in the documents were discovered that required correction according to the Manual of Patent Examining Procedure. Accordingly, a new set of documents was prepared by us and sent to the inventors for execution on January 9, 1997. The last of these documents was executed and returned to us on January 20, 1997. The necessary Assignee documents were executed February 10, 1997 and received by us February 18, 1997.
- 11. A review of our billing records indicates that since the determination that there was an error in the inventorship entity in these applications, as memorialized in our letter to the inventors on August 26, 1996, we spent a total of at least 100 hours effecting the inventorship changes. This reflects an on-going effort, on a significant scale, on this project for over five consecutive months.
- 12. As of the filing of these documents, Applicants are awaiting a second Official Action, Applicants having filed a response to the first Action on

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December 16, 1996. In that response, Applicants cancelled claims such that the remaining claims are directed to an invention as to which an inventorship determination may be made.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Respectfully Submitted/

Paul F Prestia, Reg. No. 23.031

Date

Allan M. Wheatcraft, Reg. No. 36,30

7 7 1 7 Date

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June 5, 1995

BIFURCATED ENDOLUMINAL

PROSTHESIS

2/25/97

VERIFIED STATEMENT OF FACTS, BY DR. CLAUDE MIALHE, **PURSUANT TO 37 C.F.R. § 1.48(a)**

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

- I, Dr. Claude Mialhe, an originally named inventor in the above-identified application, hereby declare as follows:
- I am one of the co-inventors of the invention claimed in this 1. application.
- Over the course of many months during the development of 2. the invention claimed in this application, I conferred about the invention only with Dr. Goicoechea and Mr. Hudson. I did not have any contact with Dr. Michael D. Dake or Dr. Andrew H. Cragg during this development, nor was I aware of any contact between any of the other originally named co-inventors and Dr. Cragg or Dr. Dake.
- I have no direct knowledge of any contribution to the 3. invention claimed in this application by either Dr. Cragg or Dr. Dake.
- Mr. Paul F. Prestia and Mr. Allan M. Wheatcraft, attorneys 4. at the law firm of Ratner & Prestia, contacted me in the Spring of 1996 to discuss my role in the development of the present invention. I submitted oral testimony and written documents to Messrs. Prestia and Wheatcraft concerning my role in the development.

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- 5. I have received from Messrs. Prestia and Wheatcraft a letter dated August 26, 1996, indicating that as a result of their investigation they had concluded that Dr. Dake and Dr. Cragg should be named as co-inventors of the invention claimed in this application. That was the first time I was made aware that Dr. Dake and Dr. Cragg were inventors who had been erroneously omitted from this application. I now understand therefore that Dr. Dake and Dr. Cragg should properly be named as co-inventors in this application.
- 6. On information and belief, the omission of Dr. Dake and Dr. Cragg as named co-inventors occurred through an innocent error without any deceptive intention on my part.
- 7. On September 5, 1994, I executed a declaration in the grandparent of this application, and on December 12, 1994, I executed a declaration in the parent application. When I executed those declarations, I had reviewed and understood the contents of the specifications including the claims, and I had reviewed the declarations prior to execution. Despite such reviews, because of my understanding of the events surrounding the development of the invention as described above, the innocent error in not naming Dr. Cragg and Dr. Dake as inventors occurred.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Respectfully Submitted,

Dr. Claude Mialhe

Jan - 16, 1997

BSI-210 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant:

G. Goicoechea et al.

: Art Unit:

3308

Serial No.:

08/463,987

: Examiner: M. Milano

Filed:

June 5, 1995

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BIFURCATED ENDOLUMINAL

PROSTHESIS

VERIFIED STATEMENT OF FACTS, BY DR. GEORGE GOICOECHEA, PURSUANT TO 37 C.F.R. § 1.48(a)

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

- I, Dr. George Goicoechea, an originally named inventor in the aboveidentified application, hereby declare as follows:
- 1. I am one of the co-inventors of the invention claimed in this application. I am also the former President of the original assignee of the parent of the present application, MinTec, Inc. One of the other co-inventors, John Hudson, is a former employee of MinTec.
- 2. Over the course of many months during the development of the invention claimed in this application, I conferred about the invention with all of the other co-inventors originally named in this application.
- 3. During the early phases of this development period, I also conferred with Dr. Andrew H. Cragg and met with Dr. Michael D. Dake. An affiliate of MinTec, Inc. had earlier taken assignment from Dr. Cragg of a related invention which Dr. Cragg had developed independently. At my request, and pursuant to a suggestion of Dr. Cragg, Dr. Dake conferred with Mr. Hudson.
- 4. On information and belief, Mr. Hudson believed that all information conveyed to him regarding the invention by Dr. Dake originated with

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Dr. Cragg. Accordingly, Mr. Hudson and I came to believe that Dr. Dake had made no original contribution to the development of the invention claimed in this and related applications.

- 5. Accordingly, communications between Dr. Dake and Mr. Hudson concerning the invention ceased.
- stage of development of the technology (and his contribution to that development is evidenced by his being named as an inventor in a related application covering the technology), and because the particular invention claimed in the present application was thought by me to have been developed after Dr. Cragg's involvement, Mr. Hudson and I believed that Dr. Cragg was not an inventor of any invention claimed in the parent (Ser. No. 08/317,763) of this application. We did believe, however, that Dr. Cragg had contributed to certain inventions of the grandparent application (Ser. No. 08/312,881). Thus, Dr. Cragg was included as a co-inventor in the European applications first filed on this technology (and upon which was based the grandparent application) and in the grandparent application.
- 7. Upon completion of the development of the invention claimed in the parent (Ser. No. 08/317,763) of the present application, I erroneously believed, as did Mr. Hudson, that neither Dr. Dake nor Dr. Cragg had contributed to the invention specifically claimed in that application. Therefore, neither were named as inventors. We did not consult with U.S. counsel Paul F. Prestia and Allan M. Wheatcraft of Ratner & Prestia regarding our conclusion on this point (we just presented it to them). Nor did we consider the relevancy of certain facts and documents that were therefore not furnished to counsel until much later, after that parent application had been filed.
- 8. Thereafter, recognizing the significance of the GATT related changes in the U.S. Patent Law and the possibility that numerous divisional applications of Serial No. 08/317,763 might be required, counsel advised and I approved the filing a number of continuation applications, including this one, just prior to that change in the law on June 6, 1995.

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9. Prior to the above referenced Dake-Hudson communications, I had met with Dr. Dake, and had discussed the possibility of his involvement in a collaborative effort which I was then organizing. I understand that in the course of those discussions, Dr. Dake believes that he disclosed to me some aspects of the invention claimed in this and related applications. I do not specifically recall such disclosures but under all of the circumstances of which I have now been made aware, I believe that such a disclosure was made.

- 10. In the spring of 1996, MinTec, Inc., sold all of its assets, including the present application, to the present assignee, Boston Scientific Technology, Inc. During the negotiations leading to the sale of these assets, a question was raised by Boston Scientific regarding the inventorship of the invention claimed in the parent of this application. Upon information and belief, Dr. Dake had made statements to others in the industry indicating that he contributed to the development of the invention.
- 11. In response to this issue raised by Boston Scientific, an investigation was conducted by attorneys Paul F. Prestia and Allan M. Wheatcraft at the law firm of Ratner & Prestia regarding the inventorship of this invention. On information and belief, all of the originally named inventors in this application and Dr. Cragg and Dr. Dake submitted documentary proof and oral testimony to Messrs. Prestia and Wheatcraft as part of this investigation.
- 12. Messrs. Prestia and Wheatcraft summarized their analysis and conclusions in a letter to me dated August 26, 1996. That letter indicated that Messrs. Prestia and Wheatcraft had concluded that Dr. Dake and Dr. Cragg should be named as co-inventors of the invention claimed in this application (which was filed before that investigation was completed). That was the first time I was made aware that Dr. Dake and Dr. Cragg were inventors who had been erroneously omitted from this application.
- 13. To the best of my information and belief, the omission of Dr. Dake and Dr. Cragg as named co-inventors occurred through error without any deceptive intention on my part.

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14. On August 29, 1994, I executed a declaration in the grandparent of this application, and on December 6, 1994, I executed a declaration in the parent application. When I executed those declarations, I had reviewed and understood the contents of the specifications including the claims, and I had reviewed the declarations prior to execution. Despite such reviews, because of my understanding of the events surrounding the development of the invention as described above, the error in not naming Dr. Cragg and Dr. Dake as inventors occurred.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Respectfully Submitted,

Dr. George Goicoechea

1/12/97

BSI-210

PATENT

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G. Goicoechea et al.

: Art Unit:

3308

Serial No.:

08/463,987

: Examiner: M. Milano

Filed:

June 5, 1995

For:

BIFURCATED ENDOLUMINAL

PROSTHESIS

VERIFIED STATEMENT OF FACTS, BY JOHN HUDSON, **PURSUANT TO 37 C.F.R. § 1.48(a)**

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

I, John Hudson, an originally named inventor in the above-identified application, hereby declare as follows:

- I am one of the co-inventors of the invention claimed in this 1. application. I am also a former employee of the original assignee of the parent of the present application, MinTec, Inc. One of the other co-inventors, Dr. George Goicoechea, was President of MinTec, Inc.
- Over the course of many months during the development of 2. the invention claimed in this application, I conferred with all of the other coinventors originally named in this application.
- During the early phases of the development, I also had 3. conferred with Dr. Andrew H. Cragg.
- For a relatively brief period of time during the development of the technology, Dr. Michael D. Dake conferred with me about the invention

pursuant to a suggestion by Dr. Goicoechea and that of Dr. Cragg, who was an acquaintance of Dr. Dake and who thought Dr. Dake might be able to assist in the development of the invention.

- 5. During my discussions with Dr. Dake, I believed that all information conveyed to me regarding the technology by Dr. Dake originated with Dr. Cragg. Accordingly, Dr. Goicoechea and I came to believe that Dr. Dake had made no original contribution to the development of the technology.
- 6. Accordingly, I ceased communication with Dr. Dake regarding the invention.
- stage of development of the technology (and his contribution to that development is evidenced by his being named as an inventor in related applications covering the technology), and because the particular invention claimed in the immediate parent (Ser. No. 08/317,763) of the present application was thought to have been developed after Dr. Cragg's involvement, Dr. Goicoechea and I believed that Dr. Cragg was not an inventor of the particular invention claimed in that application. At that time, we were not aware that certain evidence in our possession might have led counsel to a different conclusion either with respect to the invention originally claimed in the parent (Ser. No. 08/317,763) of this application as filed, or in inventions claimed later. In any event, this evidence was not then made available to the U.S. attorneys responsible for that parent (Ser. No. 08/317,763) application, Paul F. Prestia and Allan M. Wheatcraft.
- 8. Thereafter, recognizing the significance of the GATT related changes in the U.S. Patent Law and the possibility that numerous divisional applications of Serial No. 08/317,763 might be required, counsel advised the filing of a number of continuation applications, including this one, just prior to that change in the law on June 6, 1995.

- 9. In the Spring of 1996, MinTec, Inc. sold all of its assets, including rights to the present application, to the present assignee, Boston Scientific Technology, Inc. During the negotiations leading to the sale of these assets, a question was raised by Boston Scientific regarding the inventorship of the invention claimed in this application. Upon information and belief, Dr. Dake had made statements to others in the industry indicating that he had contributed to the development of the invention.
- 10. In response to this issue raised by Boston Scientific, an investigation was conducted by Messrs. Prestia and Wheatcraft regarding the inventorship of this invention. On information and belief, all of the originally named inventors in this application and Dr. Cragg and Dr. Dake submitted documentary proof and oral testimony to Messrs. Prestia and Wheatcraft as part of this investigation.
- 11. Messrs. Prestia and Wheatcraft sent me a letter dated August 26, 1996, indicating that as a result of their investigation they had concluded that Dr. Dake and Dr. Cragg should be named as co-inventors of the invention claimed in this application. That was the first time I had been made aware that Dr. Cragg and Dr. Dake were inventors who had been erroneously omitted from the application.
- 12. The omission of Dr. Dake and Dr. Cragg as named coinventors occurred through error without any deceptive intention on my part.
- 13. On August 4, 1994, I executed a declaration in the grandparent of this application, and on December 6, 1994, I executed a declaration in the parent application. When I executed those declarations, I had reviewed and understood the contents of the specifications including the claims, and I had reviewed the declarations prior to execution. Despite such reviews, because of my understanding of the events surrounding the development of the invention as described above, the error in not naming Dr. Cragg and Dr. Dake as inventors occurred.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Respectfully Submitted,

Mr. John Hudson